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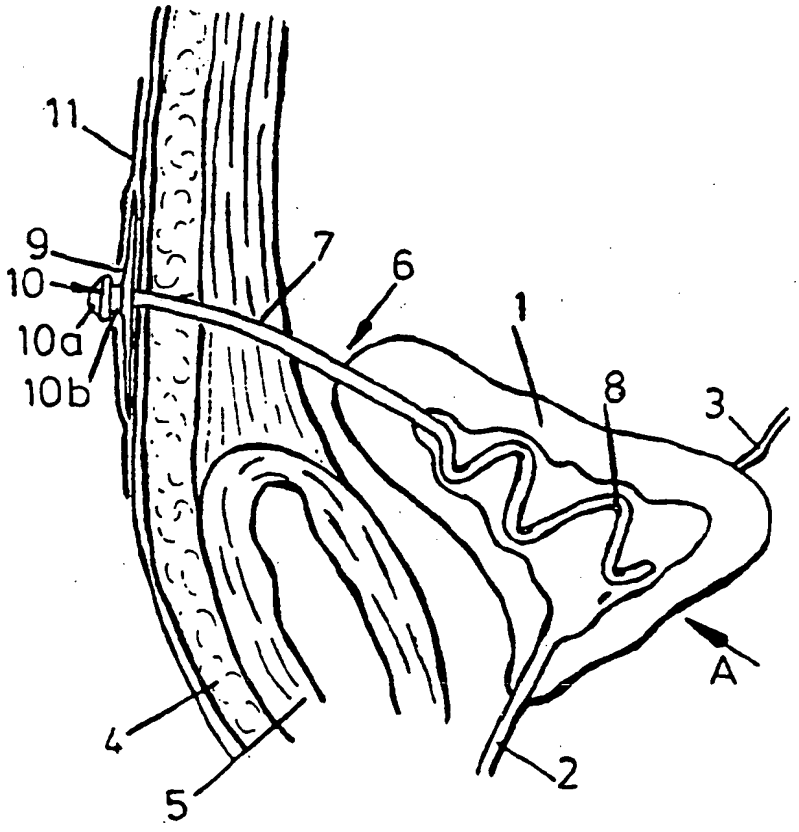
(54) Title: CATHETER

(57) Abstract

A suprapubic catheter (6) comprises a drainage tube (7) having a drainage end for location outside the patient's body. The drainage end has an enlarged head portion on which a urine collection bag (12) may be removably mounted. The catheter (6) has a disk (9) which lies against the patient's skin. A breathable dressing (11) is used to secure the disk in position and thus retain the catheter on the patient's body.



CATHETER

The present invention relates to urinary catheters, i.e. catheters for use in the drainage of urine from the bladder of a patient.

One form of urinary drainage catheter which is used extensively is a urethral catheter. As is well known, such catheters are inserted along the urethra of the patient so that a drainage tip of the catheter locates in the patients bladder.

Urethral catheters do however suffer from a number of disadvantages, as detailed below:

(i) Long term use of the catheter is associated with urinary infection owing to the presence of a foreign body within the cavity of the bladder. A biofilm forms on the surface of the catheter and bacteria become entrapped within a glycocalyx.

(ii) Leakage of urine occurs around the catheter, particularly in women, who have a short urethral passage.

(iii) The catheter can be expelled if the patient has an unstable or hyperreflexic bladder. This is most common in patients with a neurological disorder. Catheters are retained in the bladder by means of a balloon situated near its tip and the distended balloon can seriously damage the urethra when it is expelled causing further leakage around the catheter.

(iv) The self-retaining balloon requires a valve arrangement for inflation and deflation which is located externally. The distended balloon does cause the tip of the catheter to protrude into the wall of the bladder causing further irritation.

(v) The catheter can be an obstacle to sexual activity. Furthermore, the catheter and urine collection system is unaesthetic, causing distress to patients and to their carers.

A further form of catheter is a suprapubic catheter which is inserted through the wall of the patient's abdomen above the level of the pubis directly into the bladder. The catheter is usually inserted percutaneously by means of a trocar either within the catheter or within a cannula. Suprapubic catheterisation is an established and successful method for short or long term drainage of the bladder. However, catheterisation, whether this is urethral or suprapublic, suffer from many of the same disadvantages with infection, recurrent blockage and stone formation. The object of this invention is to

obviate the problem of catheter blockage and to provide a more aesthetic form of catheterisation in this group of disabled people so that suprapubic catheterisation becomes an attractive option for long term drainage.

According to the first aspect of the present invention there is provided a suprapubic catheter comprising a drainage tube having a urine collection end for location in the bladder of a patient and a urine exit end for location externally of the body of the patient wherein the urine collection end has an enlarged head portion for the securement of a urine collection bag to the catheter, and said catheter is further provided with a flange provided around the tube behind the head portion, said flange serving for use in securement of the catheter on the patient's body by means of adhesive material.

According to a second aspect of the present invention there is provided a suprapubic catheterisation system comprising a catheter as defined in the preceding paragraph and a drainage bag having an inlet fixture which is a releasable push fit onto said head of the catheter.

The catheter of the invention is intended to be secured in position by an adhesive material which is attached to both the flange (which lies against the patient's body) and the skin of the patient around the flange. This means of securement is perfectly adequate to support and retain the catheter on the patient's body without the need for any retaining means (e.g. a balloon) locating within the bladder. Thus possible damage to the bladder by the action of such means is avoided. Furthermore the need for valves on the catheter for use in controlling and maintaining the inflation of a balloon is avoided.

The adhesive material should be breathable to prevent sweating. Most preferably the adhesive material has a MVTR equal to or greater than that of intact skin. The adhesive material preferably has an MVTR of 500-1200 g m^{-2} $24hr^{-1}$.

The flange on the catheter is most preferably of a relatively supple material which will conform to the shape of the patient's body around the stoma through which the catheter is inserted.

Conveniently the flange is provided by a flat, material which completely surrounds the drainage tube. This has the advantage that the material may be effective to isolate the patient's skin from the urine collection bag thus avoiding contact of urine with the skin.

The drainage tube is preferably of a supple material so as to accommodate movement of the patient and not to cause damage to the bladder or overlying tissues.

The drainage tube is preferably of polyurethane as such material (in addition to being supple) is less prone to encrustation over a long period of use. Preferably also the outer surface of the drainage tube is provided with a hydrophilic coating to prevent irritation resulting from relative movement of the drainage tube through the wall of the bladder.

Preferably the urine collection end is generally spiral or serpentine with drainage apertures being provided on the inside of the turns.

Preferably also the head of the urine exit end of the drainage tube is adapted to be a releasable "popper type" fit on the urine collection bag.

The bag preferably has an inlet arrangement provided with two rings in generally face-to-face relationship between which the head of the drainage tube locates. The outer ring is preferably of a semi-rigid plastics material and is of a shallow cup shape which opens on the side adjacent the inner ring. The inner ring is of a stiff resilient plastic and is normally flat but is deformable upon insertion of the enlarged head portion of the catheter into the inlet arrangement so as to seal against the head portion. Preferably also the head is spaced slightly from the flange so that the outer one of said rings is a close fit therebetween, allowing the bag to sit against the patient's skin.

The invention will be further described by way of example only with reference to the accompanying drawings, in which

Fig. 1 diagrammatically illustrates one embodiment of suprapubic catheter in accordance with the invention (but omitting details of a urine collection bag) inserted in the bladder of a patient;

Fig. 2 is a view to an enlarged scale of the catheter as seen in the direction of arrow A in Fig. 1; and

Fig. 3 illustrates the use of a urine collection bag in conjunction with the catheter illustrated in Fig. 1.

Fig. 1 illustrates a portion of the abdominal region of a patient. The anatomical features illustrated in this drawing include the bladder

1 with associated urethra 2 and ureter 3, the abdominal wall 4 and the pubis bone 5.

Fig. 1 also illustrates a suprapubic catheter 6 located in position for drainage of the bladder 1.

Catheter 6 includes a drainage tube 7 fabricated from supple polyurethane. Tube 7 has a urine exit end (locating externally of the patient's body) connected to a urine collection end (locating within the patient's bladder) by an intermediate section of the catheter extending through the bladder wall and abdominal wall 4. The urine collection end of the catheter 6 is in the form of a slightly "flattened" coil (see also Fig. 2) having drainage apertures 8 provided on the inside of the turns of the coil.

Tube 7 is provided with a hydrophilic coating in the manner known in the art.

At its urine exit end, a conformable disk 9 is located over the end of tube 7 which (at this end) is provided with a head 10. This head has an axial bore by which the head is located on tube 7. The head 10 has a generally frustoconical end portion 10a connected to a generally cylindrical body portion 10b which abuts against disk 9.

Disk 9 lies against the skin of the patient and is retained in position by a moisture transmissive dressing 11 having an aperture such that the inner edge of the dressing (i.e. that edge defining the aperture) overlies the outer edge of disk 9. Dressing 11 comprises a breathable film (preferably of polyurethane) having an adhesive layer (e.g. a patterned layer) which allows the dressing to be breathable.

Ideally dressing 11 has a moisture transmission rate at least equal to that of human skin.

A urine collection bag 12 is provided as shown in Fig. 3. This bag has an inlet 13 provided with a fixture 14 formed of inner and outer apertured rings (14a and 14b respectively). Ring 14b is of a shallow cup shape and is of semi-rigid plastics material. Ring 14a is of a stiff resilient plastic which prior to insertion of the head is generally flat. A slit is formed in the material of the bag 12 so as to form a flap 14c which overlies the aperture of ring 14a. Fixture 14 is such as to be capable of receiving head 10 of the catheter as a "popper-type" push fit through the aperture of ring 14b, and of releasably retaining the head between the rings 14a and 14b. With

head 10 located in fixture 14, the inner marginal edge of ring 14b is a close fit between the frustoconical portion 10a (of head 10) and the disk 9. Furthermore, the frustoconical portion 10a abuts against ring 14a to deform the latter and provide a degree of liquid sealing around the head 10. With the head so located in position, the flap 14c is open to allow urine to drain into the bag. When the head is removed, the plastic ring 14a again lies flat and its aperture is overlaid by flap 14c to close the bag.

A drainage tap 15 is provided at the base of bag 12 which is supported on the patient's body by a further breathable dressing 16.

It will be appreciated that the illustrated catheter is retained in position by virtue of the breathable dressing 11 holding disk 10 in position against the patient's skin. This avoids the need for a balloon or other fixture arrangement provided on the catheter within the bladder. Consequently there will be no damage to the bladder resulting from any movement of the catheter outwardly of the bladder, such as can occur in the case of catheters provided with balloons.

The location of the drainage apertures 8 on the inside of the turns of the coil prevent the soft lining of the bladder contacting and blocking the apertures 8.

The inlet of the urine collection bag 12 is isolated from the patient's skin by the presence of the disk 9 thereby avoiding problems caused by contact of urine with the skin. Furthermore the bag is supported partly by the head portion 10 and partly by the dressing 16. Thus the need for more complicated bag fixing arrangements is avoided.

If desired the bag 12 may be removed for short periods of time and replaced by a small sealing cap to allow bathing or other activities.

CLAIMS

1. A suprapubic catheter comprising a drainage tube having a urine collection end for location in the bladder of a patient and a urine exit end for location externally of the body of the patient wherein the urine exit end has an enlarged head portion for the securement of a urine collection bag to the catheter, and said catheter is further provided with a flange provided around the tube behind the head portion, said flange serving for use in securement of the catheter on the patient's body by means of adhesive material.

2. A catheter as claimed in claim 1 wherein the flange is of a relatively supple material.

3. A catheter as claimed in claim 2 wherein the flange is provided by a flat material which completely surrounds the drainage tube.

4. A catheter as claimed in any one of claims 1 to 3 wherein the drainage tube is of a polyurethane.

5. A catheter as claimed in any one of claims 1 to 4 wherein the urine collection end is generally spiral or serpentine with drainage apertures being provided on the inside of the turns.

6. A catheter as claimed in any one of claims 1 to 5 wherein the enlarged head portion has a frustoconical end region connected to a generally cylindrical body portion abutting against the disk.

7. A suprapubic catheterisation system comprising a catheter as defined in any one of claims 1 to 6 and a drainage bag having an inlet fixture which is a releasable push fit onto said head of the catheter.

8. A system as claimed in claim 7 wherein the head of the urine exit end of the drainage tube is adapted to be a releasable "popper-type" fit on the urine collection bag.

9. A system as claimed in claim 8 wherein the bag has an inlet

arrangement provided with two rings between which the head of the drainage tube locates.

10. A system as claimed in claim 9 wherein the outer ring is of a relatively rigid plastics material and the inner ring is of a relatively more flexible plastics material adapted to seal against the head portion when the catheter is inserted in the bag.

11. A system as claimed in claim 9 or 10 wherein a slit is formed in the material of the bag to form a flap adapted to overlie the aperture of the inner ring when the bag is detached from the catheter.

12. A system as claimed in any one of claims 9 to 11 wherein the head is spaced slightly from the flange so that the outer one of said rings is a close fit between said head and the flange.

13. The combination of a catheter as claimed in any one of claims 1 to 6 or a suprapubic catheterisation system as claimed in any one of claims 7 to 10 and a breathable adhesive material for attaching said flange to the skin of the patient.

14. The combination as claimed in claim 13 wherein the adhesive material has an MVTR at least equal to that of intact human skin.

15. A suprapubic catheter substantially as hereinbefore described with reference to the accompanying drawings.

16. A suprapubic catheterisation system substantially as hereinbefore described with reference to the accompanying drawings.

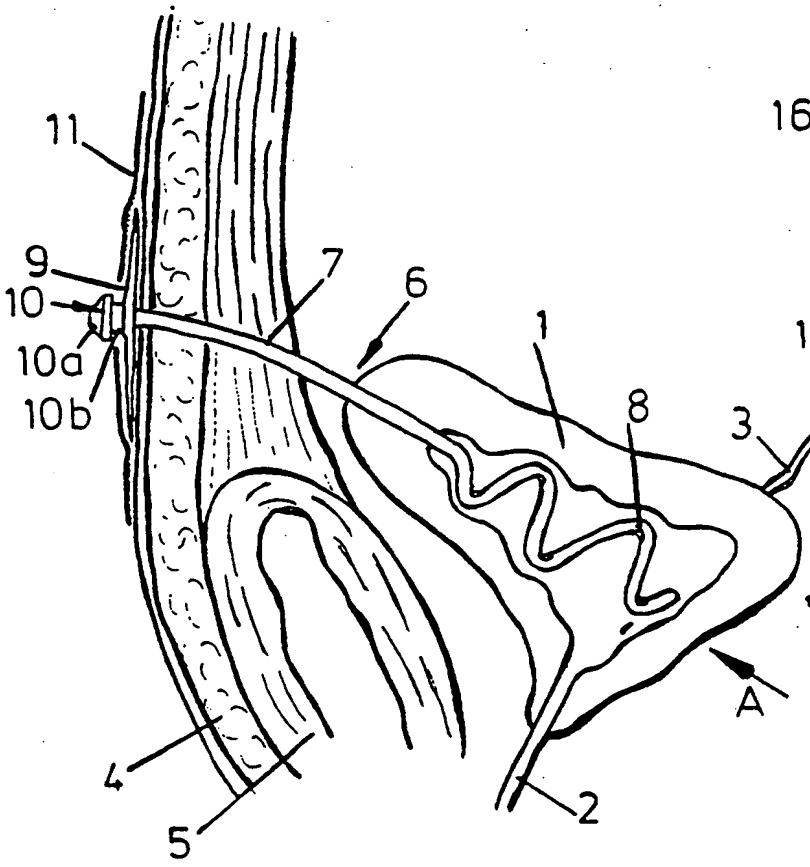


FIG. 1

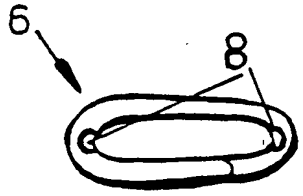


FIG. 2

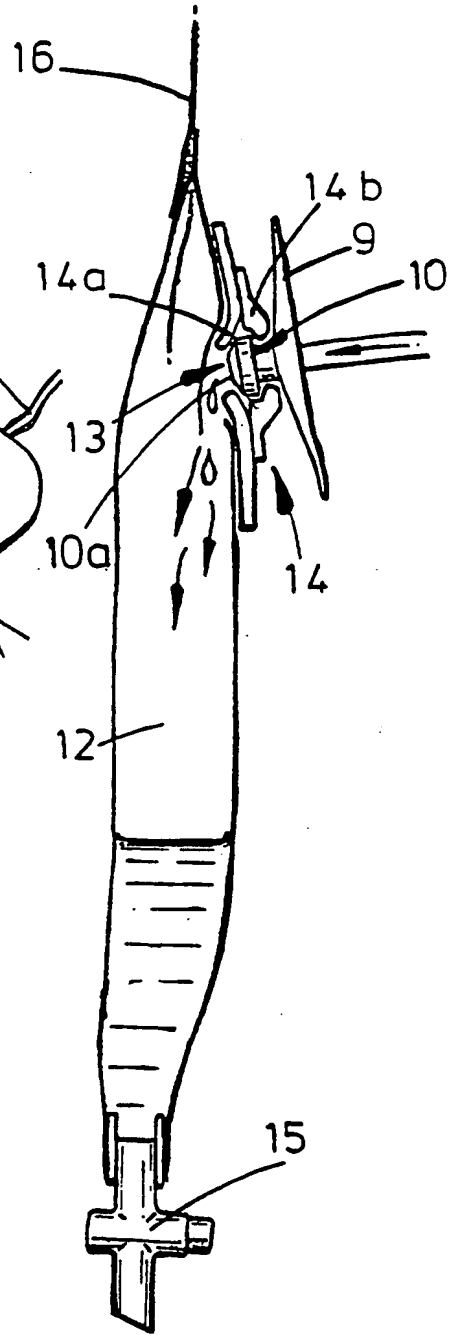


FIG. 3

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(72) Inventors; and
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(74) Agent: ATKINSON, Peter, Birch; Marks & Clerk, Suite 301, Sunlight House, Quay Street, Manchester M3 3JY (GB).

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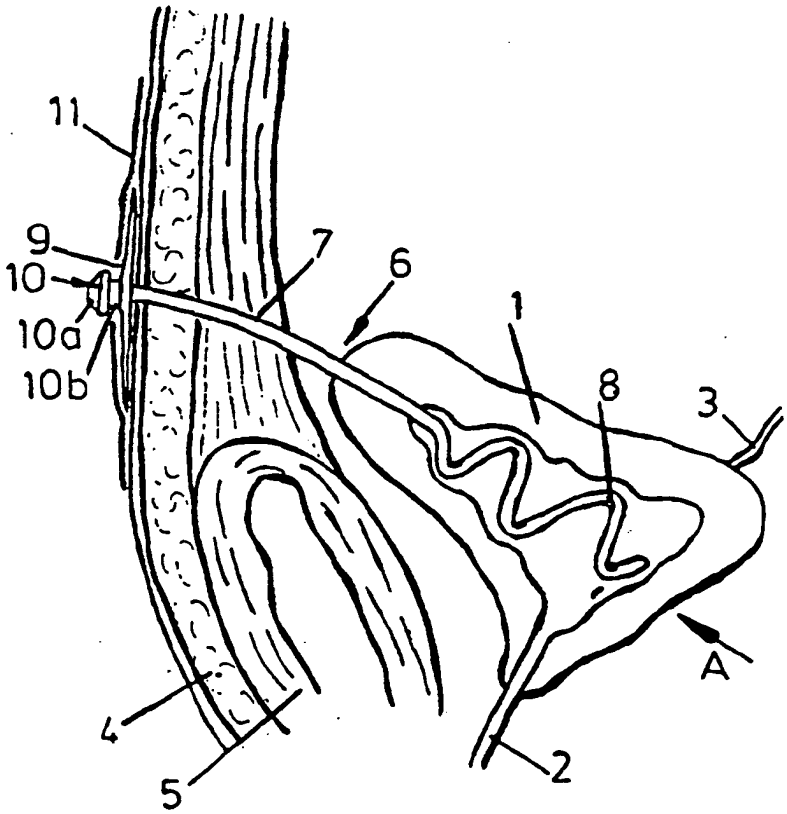
(54) Title: CATHETER

(57) Abstract

A suprapubic catheter (6) comprises a drainage tube (7) having a drainage end for location outside the patient's body. The drainage end has an enlarged head portion on which a urine collection bag (12) may be removably mounted. The catheter (6) has a disk (9) which lies against the patient's skin. A breathable dressing (11) is used to secure the disk in position and thus retain the catheter on the patient's body.



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Int. ional Application No
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,5 045 075 (ERSEK) 3 September 1991 see column 5, line 31 - column 6, line 60; figure 1 AND 11	1-4,6-13
Y	US,A,4 443 219 (MEISCH ET AL.) 17 April 1984 see column 3, line 65 - column 4, line 25; figure 3 AND 4	1-4,6-13
A	US,A,4 786 285 (JAMBOR) 22 November 1988 see column 2, line 40 - column 4, line 15; figure 1 AND 2	1,7,10
A	US,A,4 946 451 (CIANCI) 7 August 1990 see column 3, line 28-55; figures 1,6,8	11
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Date of the actual completion of the international search	Date of mailing of the international search report
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PCT/GB 94/02237

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 205 830 (DASSA ET AL.) 27 April 1993 see column 3, line 12-33; figure 2	5
A	US,A,4 280 498 (JENSEN) 28 July 1981 see column 6, line 48-61; figure 2 ET 3	1,8,12
A	GB,A,2 203 125 (CRAIG MEDICAL PRODUCTS LIMITED) 12 October 1988 see page 3, line 14-22; figure 4	1,10,12
A	US,A,4 579 120 (MAC GREGOR) 1 April 1986 see column 4, line 11-50; figures 2-4	1,13

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/GB 94/02237

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5045075	03-09-91	NONE		
US-A-4443219	17-04-84	AU-A-	8123082	16-09-82
		DE-A-	3208429	30-09-82
		FR-A-	2501499	17-09-82
		JP-A-	57160454	02-10-82
		NL-A-	8200743	01-10-82
		SE-A-	8200765	11-09-82
US-A-4786285	22-11-88	AU-B-	601526	13-09-90
		AU-A-	8208787	23-06-88
		DE-A-	3741599	30-06-88
		FR-A-	2608419	24-06-88
		GB-A,B	2198953	29-06-88
		IE-B-	60543	27-07-94
		JP-C-	1821084	27-01-94
		JP-B-	5028146	23-04-93
		JP-A-	63160647	04-07-88
		ZA-A-	8709169	03-06-88
US-A-4946451	07-08-90	US-A-	4526576	02-07-85
US-A-5205830	27-04-93	NONE		
US-A-4280498	28-07-81	AU-B-	533306	17-11-83
		AU-A-	6343680	30-04-81
		CA-A-	1160124	10-01-84
		CA-A-	1160126	10-01-84
		DE-A-	3039859	30-04-81
		FR-A,B	2474858	07-08-81
		FR-A,B	2474859	07-08-81
		GB-A,B	2061466	13-05-81
		GB-A,B	2125130	29-02-84
		JP-B-	1009865	20-02-89
		JP-C-	1522445	12-10-89
		JP-A-	56066265	04-06-81
		SE-B-	448514	02-03-87
		SE-A-	8007163	23-04-81
GB-A-2203125	12-10-88	AU-B-	615648	10-10-91

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/GB 94/02237

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
GB-A-2203125		AU-A-	1407888	13-10-88
		CA-A-	1293662	31-12-91
		DE-A-	3876834	04-02-93
		EP-A,B	0286334	12-10-88
		JP-A-	63290579	28-11-88
		NO-C-	173320	01-12-93
		NZ-A-	224034	27-04-94
		NZ-A-	243088	27-04-94
		US-A-	4925[illegible]6	15-05-90
		ZA-A-	8802218	21-09-88
US-A-4579120	01-04-86	NONE		